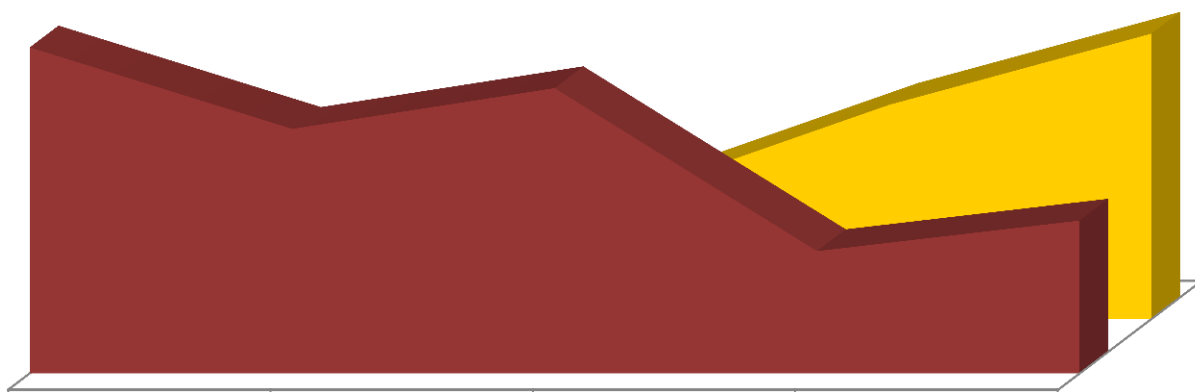


Strengthening Pharmaceutical Systems

ETHIOPIA ANNUAL REPORT

October 1, 2010—September 30-2011



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Strengthening
Pharmaceutical
Systems

Strengthening Pharmaceutical Systems–Ethiopia Annual Report: October 1, 2010–September 30, 2011

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November 2011



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About SPS

The Strengthening Pharmaceutical Systems (SPS) Program strives to build capacity within developing countries to effectively manage all aspects of pharmaceutical systems and services. SPS focuses on improving governance in the pharmaceutical sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to and appropriate use of medicines.

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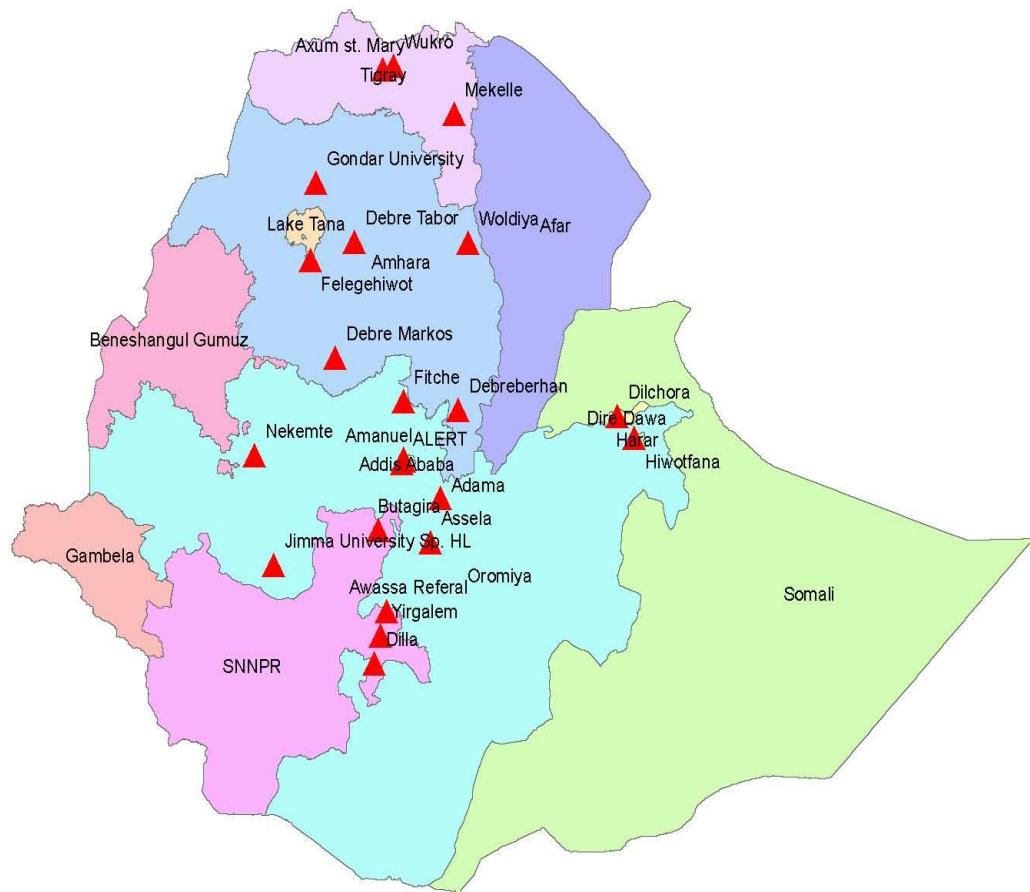
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ACRONYMS AND ABBREVIATIONS

ACT	artemisinin-based combination therapy
ADR	adverse drug reaction
ADT	antiretroviral dispensing tool
AMR	antimicrobial resistance
APTS	auditable pharmacy services and transaction system
ARV	antiretroviral
COP	Country Operating Plan
CTO	Cognizant Technical Officer
DI	drug information
DIS	Drug Information Services
DUE	drug use evaluation
DTC	Drug and Therapeutics Committee
E.C.	Ethiopian Calendar
EDT	electronic dispensing tool
EHRIG	Ethiopian Hospital Reform Implementation Guidelines
EPA	Ethiopian Pharmaceutical Association
FMHACA	Food, Medicines and Health Care Administration Authority
FMOH	Federal Ministry of Health
HSDP	Health Sector Development Program
ICAP	International Center for Health Care and Treatment Program
I-TECH	International Training and Education Center for Health
IMAI	Integrated Management of Adolescent and Adulthood Illnesses
IPLS	Integrated Pharmaceutical Logistics Systems
JHU	Johns Hopkins University
MOU	memorandum of understanding
MSH	Management Sciences for Health
ORHB	Oromia Regional Health Bureau
PFSA	Pharmaceutical Fund and Supply Agency
PMIS	Pharmaceutical Management Information System
PV	pharmacovigilance
RDV	Rural Drug Vendor
RHBs	regional health bureaus
RMU	rational medicines use
SCMS	Supply Chain Management System
SPS	Strengthening Pharmaceutical Systems
TA	technical assistance
UMC	<i>The Uppsala Monitoring Center</i>
USG	US Government
WHO	World Health Organization
ZHO	Zonal Health Office



Ethiopian Hospital Reform Implementation Guidelines (EHIG) sites

OVERVIEW

The Strengthening Pharmaceutical Systems (SPS) program in Ethiopia contributes towards meeting specific US President's Emergency Plan for AIDS Relief (PEPFAR) and the President's Malaria Initiative program targets by providing technical support to facilities that provide antiretroviral therapy (ART) and selected artemisinin-based combination therapy (ACT) services for the appropriate dispensing and rational medicines use (RMU), including maintenance of a pharmaceutical management information system (PMIS). SPS plays an important role in assuring the sustainability of interventions by strengthening human resource capacity and introducing robust systems for patient-oriented pharmacy services in health facilities.

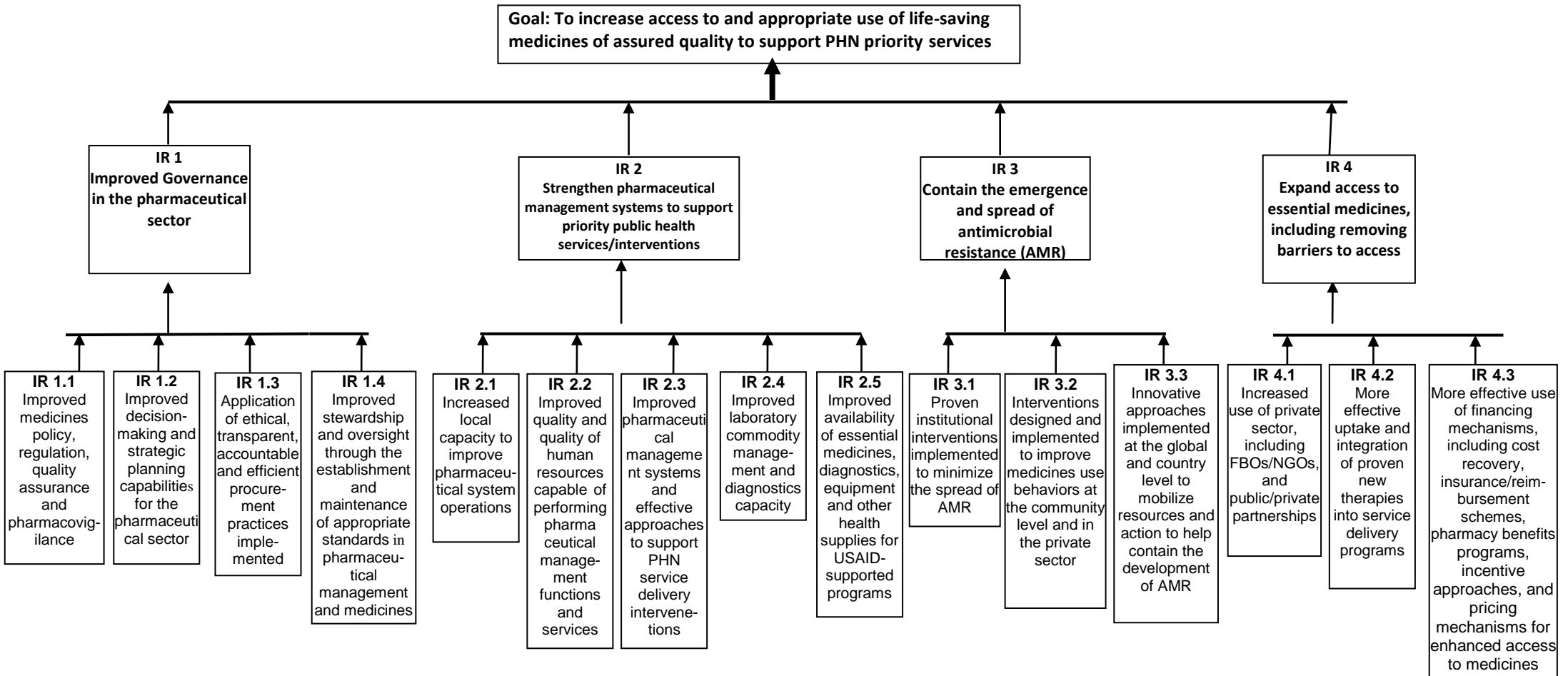
Similarly, SPS builds institutional capacity by providing technical assistance and resources to key pharmacy stakeholders, such as the Food, Medicines and Health Care Administration Authority (FMHACA), the Pharmaceutical Fund and Supply Agency (PFSA), schools of pharmacy, the Ethiopian Pharmaceutical Association (EPA), and the regional health bureaus (RHBs). SPS has been providing support to FMHACA to strengthen governance in the pharmaceutical sector by improving policies, laws, and regulations; standardizing and streamlining work procedures, and also through developing standards and facilitating discussions with relevant stake holders. With PFSA and the regional health bureaus, SPS has been engaged in improving the pharmaceutical services of health facilities by promoting the rational drug use.

Ethiopia's Federal Ministry of Health (FMOH) has been leading a sector-wide reform effort aimed at significantly improving the quality and accessibility of services at all levels of the country's decentralized health system. As part of this reform, the ministry developed the Ethiopian Hospital Reform Implementation Guideline (EHRIG) in which SPS played the lead role in developing the pharmacy chapter and assisted health facilities to implement some aspects of the chapter, that are intended to improve the quality of patient care.

The SPS goal of increasing access to and appropriately using lifesaving medicines of assured quality to support Center for Population, Health and Nutrition priority services consists of four intermediate results relating to—

- Strengthening governance in the pharmaceutical sector by improving medicine policies, laws, and regulations, including system-based approaches to promote transparency and accountability and reduce the vulnerabilities to corruption
- Strengthening the pharmaceutical management components of health systems to support public health services, including building the capacity of individuals, institutions, and networks to manage medicines appropriately
- Containing the emergence and spread of antimicrobial resistance (AMR) and improving the use of medicines in the public and private sectors through institutional, educational, managerial, regulatory, and behavior change interventions
- Expanding access to essential medicines through the increased use of the private sector organizations and health facilities, effective integration of new health technologies, and innovative financing and insurance approaches

SPS KEY RESULTS FRAMEWORK



Under Country Operating Plan FY 2010 (COP10), SPS continued its support to governmental and nongovernmental organizations and health facilities as well as professional associations in all aspects of patient-focused pharmaceutical management systems for sustained results. SPS support is broadly focused on—

1. Promoting RMU and safety
2. Strengthening the managerial, organizational and human resource capacity of prime partners to effectively manage pharmaceutical systems and services in Ethiopia,
3. Strengthening the national capacity for the safe, accountable and timely disposal of pharmaceutical waste at the central and regional levels
4. Improving the quality of services provided by rural drug vendors (RDVs)
5. Strengthening the PMIS

This report summarizes the major activities accomplished by SPS–Ethiopia in collaboration with government of Ethiopia stakeholders and other partners during the period from October 2010 to September 2011.

ACCOMPLISHMENTS AND SUCCESSES

Pharmacy Chapter of the Ethiopian Hospital Reform Implementation Guideline

Ethiopia's FMoH has been leading a sector-wide reform aimed at improving the quality and accessibility of services at all levels of the country's decentralized health system. As part of this reform, the ministry developed the EHRIG. The guidelines focus on selected management functions of hospitals, including Pharmacy Services. SPS is a major supporter for implementation of the pharmacy services.

One effort has been to technically support hospitals to identify medicine use problems and implement rational medicine use, as well as performing ABC and VEN analysis to help hospitals allocate the lion's share of their budget for the life saving and essential medicines to the service.



Nineteen hospitals have started implementation of the EHRIG, which is 95 percent of the total targeted 20 facilities for the budget year. This was achieved in part by the favorable working relationship that SPS created with rural health bureaus (RHBs) and the vision and leadership of chief executive officers/hospital management and pharmacy professionals to improve pharmacy services by implementing EHRIG and auditable pharmacy services and transaction system (APTS).

In 2010–2011, onsite orientations on how actively participating Drug and Therapeutics Committees (DTCs) can investigate medicine use (RMU) practically, how to implement EHRIG pharmacy standards, and how to use the electronic dispensing tool (EDT), Drug Information Service (DIS), and auditable pharmacy services and transaction system (APTS) was given to management teams, DTC members, and the hospital's department heads at the country's 19 major hospitals. Hospital staff attended most of the meetings and representatives of the respective RHBs and regional FMHACA forwarded the keynote address to participants on the areas of joint interventions to improve pharmacy service in the regions.

After the presentations on pharmacy service-related issues, participants discussed the issues. In all hospitals, implementing team members have agreed to work in a coordinated way to improve pharmacy services; responsibility was given to clinicians and DTC members and secretaries to support pharmacy staff in data entry for ABC analysis and prescription review. Similarly, 2,000 copies of the EHRIG pharmacy chapter were printed and distributed by SPS to 40 health facilities, including the EHRIG sites.

A workshop on regional experiences was held at Debremarkos Hospital to scale-up EHRIG implementation to the rest of hospitals in Amhara region and to introduce the

newly designed APTS. The workshop was organized by Amhara Regional Health Bureau in collaboration with SPS.



APTS is a system designed to allow pharmacy services and transactions to be tracked in an auditable form so they can be measured against STGs, and international WHO indicators to realize rational drug use and best pharmaceutical services. As the name implies, APTS has two parts—auditable pharmacy services and an auditable pharmacy transactions systems. APTS enables pharmacy and finance professionals in the hospital to track all

medicine transactions in the pharmacy on daily basis, check for accuracy of drug prices and pharmaceutical service quality, and make the transaction transparent, accountable, and auditable. The system is created by SPS in collaboration with Debre Markos Hospital management, Amhara Regional Health Bureau, and Amhara Bureau of Finance and Economic Development, and is compatible with the EHRIG.

APTS has been successfully implemented at Debre Markos referral hospital using new and standard vouchers (model 19, model 22, and cash sales ticket) after approval by Amhara Regional Health Bureau and Bureau of Finance and Economic Development, and a scale-up of APTS to other facilities in the region and beyond is underway. Among the 12 standards in the EHRIG, APTS covers 7 pharmacy standards. It is believed that interventions taken to improve pharmacy services at Debre Markos Hospital will serve as a model to other regional facilities and could be replicated in other regions of the country. This effort has been recognized by officials from FMoH, representatives of Amhara Regional Health Bureau and 17 of its hospitals as well as professionals from Tigray Regional Health Bureau, and some of its hospitals. In addition to providing accurate information on hospital expenditure on medicines and other supplies, APTS is proving to be an important tool to curb the leakage of medicines and supplies from hospitals.



Orientation on recording and reporting procedures using newly introduced formats (vouchers) has been given to dispensers, store keepers, cashiers, and accountants assigned to handle the new system.

As part of institutionalizing APTS and giving it a legal framework for implementation in the entire Amhara region, a workshop was organized with assistance from SPS by the regional health bureau in collaboration with finance bureau and audit bureau to draft a proclamation entitled “System for Pharmaceutical Transactions and Service Provision in Amhara Regional State.” The proclamation is waiting for approval by the regional council.

The effective implementation of the system at Debre Markos Referral Hospital has encouraged Dill Chora Hospital of Dire Dawa city administration to make similar request to SPS for technical and material assistance to implement EHRIG and improve systems of pharmacy service provision in general and problems associated with pharmaceutical transactions in particular.

Support Drug and Therapeutics Committees at Health Facilities

The DTC can undertake and coordinate key activities within a health facility to promote the rational and cost-effective use of medicines. DTCs provide a forum to allow all professionals to work together toward improving health facility's services. As such, DTCs may be regarded as a tool for promoting more efficient RMU. In many developed countries, a well-functioning DTC is regarded as one of the most effective structures in health facilities to address medicine use problems.

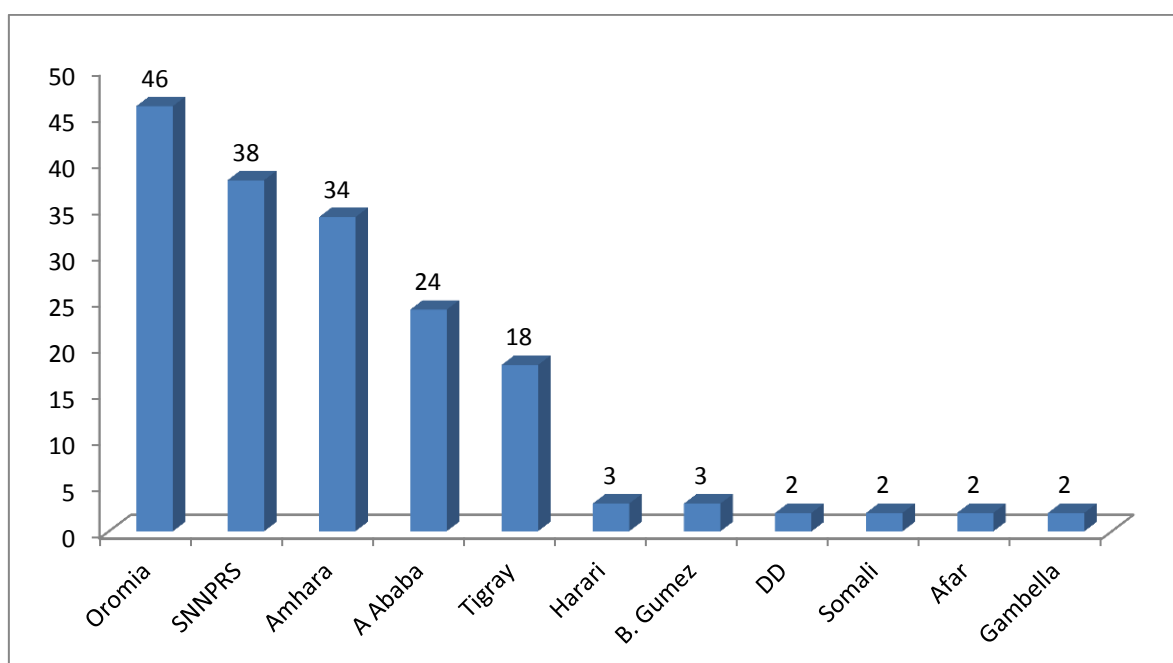


Figure 1. Number of DTCs by region, October 2011

SPS, in collaboration with Ethiopian government stakeholders, has been supporting health facilities in establishing and strengthening DTCs. In the reporting period, health facilities were given technical support to conduct meetings on DTCs; facility staff members were also sensitized on the need for the committee and its benefits. SPS, in collaboration with PFSA, supported 174 health facilities (88 hospitals and 86 health centers) to establish DTCs throughout the country (87 percent achievement).



Drug list development workshop participants at Shambu hospital

Facility-specific medicine lists are important to promote RMU, properly utilize scarce resources, and avoid wastage. SPS has been supporting health facility DTCs technically and materially to develop facility-specific medicine lists. In the reporting period, medicine list development workshops were organized by 26 hospitals to enrich the draft lists developed by hospital DTCs based on established criteria, such as disease pattern, safety, efficacy, quality, availability, and affordability of medicines. These

workshops were attended by health professionals, mainly DTC members, staff representing different hospital departments, and professionals from the RHBs, zonal health offices, and PFSA. The workshops helped participants to appreciate the benefits of DTC in improving medicine supply management, minimizing expiry, and increasing patient satisfaction. Likewise, a total of 26 facility-specific medicine lists have been printed and handed over to the respective health facilities. So far, SPS has supported the development and printing of 6 facility specific formularies and 38 medicine lists (73.3 percent of the plan has been achieved).

Recognizing the importance of DTCs and the problems related to a lack of integration of DTC activities into the routine health facility activities and the lack of “ownership” by many health facilities, the EHRIG of FMoH and the Health Facility Regulatory Standards that are under development by FMHACA have dealt with DTCs as one of the key technical committees in hospitals and health centers. In line with this, the strategic document that was developed by PFSA in collaboration with SPS to institutionalize DTCs in Ethiopia’s health care system is still at draft stage and waiting for PFSA’s responses to organize national and regional workshops for further enrichment and endorsement by the FMoH and PFSA.



Pharmacists Training at Hawassa University Ref Hospital

Realizing the needs of key users—physicians, pharmacists, nurses, and consumers—SPS formulated a strategy to meet these needs by helping facilities to set up a DIS that provides current and unbiased information on medicines and their use. The purpose of drug information services is to provide accurate, current, and unbiased information for the promotion of rational medicine therapy, and to serve health care professionals in Ethiopia by answering questions on medicine use.

To date, 19 DISs have been established in six regions of the country (95 percent of the target). Drug information pharmacists have been assigned on a full-time basis and are currently answering drug-related queries in addition to providing educational information on drug use, interactions, and new or withdrawn drugs by e-mailing the information to the medical staff or by posting the information on a notice board. A standard operating procedure to govern the

activities of DISs was also provided by SPS. SPS has since received requests from various health facilities to help them establish drug information services.

Bole Health Center is the first health facility at the health center level that has



*Mr. Anthony Boni's visit of the DIS
at Bole HC a*

realized the need for effective medicine information. SPS supported the request of the health facility for technical assistance and equipment to set up a DIS. SPS technical assistance included onsite training for the health center's DI pharmacists on systematic approach to answering drug information. Basic furniture for the DIS room, reference materials, external hard disk, stationary, white board and accessories, bookshelves, and filing cabinets have been distributed to this and 19 other sites throughout Ethiopia.

Improve the Quality of Services Provided by Rural Drug Venders

Rural drug shops are the lowest level drug retail outlets in Ethiopia, but they serve the majority of the Ethiopian population. These shops operate predominantly in rural settings and they dispense medicines according to a list approved by the regulatory body (FMHACA). For the majority of Ethiopia's rural population, the RDV is the most accessible health care provider to most Ethiopians where he or she

gets pharmaceutical as well as "clinical" services. Taking into consideration the scope of the services provided by RDVs and the number of beneficiaries of their services, SPS in collaboration with FMHACA and Oromia Regional Health Bureau (ORHB) initiated a program to improve the quality of service and access to essential medicines provided to the rural population through trainings provided to RDVs.



Training participants

As part of this intervention, SPS supported the FMHACA in its work to develop the first Rural Drug Vender (RDV) formulary. The formulary was enriched at a consultative workshop in which experts from the Faculty of Medicine and School of Pharmacy, Addis Ababa University; FMHACA, SPS, and professionals from selected hospitals participated. The developed RDV formulary and RDV medicines list were printed and distributed to RDVs by SPS. The formulary is expected to be used as an important and basic information source about medicines that RDVs are allowed to dispense and as a quick reference to all dispensers working in rural drug shops.

Under COP10, it was planned to provide trainings to 200 RDVs drawn from Oromia Region in five training sessions. The main purpose of the training was to bring changes in the skills of RDVs concerning drug supply management and RMU general, and to improve their drug handling, storage, and inventory management system; dispensing and counseling practices; minimize pharmaceutical waste; and improve handling and disposal of expired drugs. Special emphasis was put on the

handling and management of antimalarial drugs. SPS developed a RDV training curriculum, training materials, and job aids for this purpose.



Group work

Seven RDVs training sessions for trainees from different zones and towns of Oromia Region were successfully executed during the reporting period. A total of 217 RDVs of the planned 200 RDVs (109 percent) attended these training sessions. As a result of the need for such training and demand from the ORHB, two additional rounds of trainings were organized.

The majority of the trainees (72 percent) were health assistants and nurses. Surprisingly, a significant number of the trainees were found to be relatively well qualified (public health experts, health officers, nurses, and druggists).

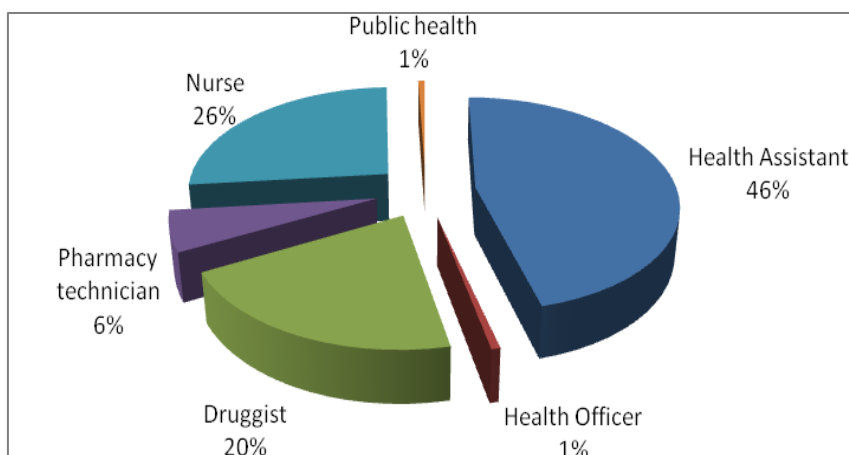


Figure 2. Percentage of distribution of professional mix of trainees

In addition, 46 experts/officials from the regulatory office of the zonal health department and FMHACA showed up for the training. These professionals were branch heads (FMHACA), process owners, and senior experts in the regulatory office responsible for supervision, inspection, and licensing activities. Inclusion of these experts is believed to be vital to create a link between the trained RDVs and the regulatory departments of the zonal health offices to facilitate the inspection, licensing, and supervision work as requested by the ORHB. Moreover, the presence of officials/experts from the regulatory body had created the opportunity to provide answers to questions that were raised by RDVs.



Certificate award to participants of RDV training

Curriculum for the RDVs training was developed by SPS, FMHACA, and ORHB experts. The curriculum focused on drug supply management and RMU and covered the following specific topics—

- Overview of the pharmaceutical sector
- Findings of the baseline survey on RDVs
- Official list of medicines for RDVs
- Properties and handling of selected medicines from the RDV list
- Safe use of medicines
 - Adverse drug reactions (ADR) and pharmacovigilance
 - AMR and prevention of AMR
- Good dispensing and counseling practices—improving communication skills of dispensers at RDV level
- Using standard medicine, dispensing, and counseling guides
- General concepts about drug supply system
 - Proper storage and supply arrangements
 - Stock rotation and drugs instability
 - Inspection/receiving of procured medicines
 - Inventory management and record keeping by RDVs
 - Pharmaceutical waste management
 - Pharmacy law and ethics: regulatory requirements for RDVs
- Malaria situation in Ethiopia—past and current programs; diagnostics and treatment
 - Classification and basic pharmacology of antimalarial medicines

Training participants appreciated the training program and promised to implement what they had learned and improve the services of RDVs. They commented, “...it is training that changes human behavior and not strict control; we have heard and learned lots of new developments in the pharmaceutical sector and shall try to improve our practice....”

Though the training’s outcome will be formally measured and assessed at a later stage, early successes and preliminary achievements of the RDVs capacity building efforts have been examined by the following output indicators—

- High training attendance level
- Positive comments from the post-training evaluation
- Tangible changes in knowledge documented through post-training supportive supervisions to RDVs

- Development of RDV formulary, which was an important component of the program's success
- Access to important policy and reference materials
- Participants have been encouraged to attend higher teaching institutions to upgrade their education and obtain certificate of competence
- Clear understanding of their roles and responsibilities (and potential opening of communication) after face-to-face discussions with regional and federal decision makers
- Networking with each other for future collaboration and formation of a professional association



Trained RDV from South West Shewa Zone

Regional FMHACA and SPS office staff members in collaboration with zonal health offices made joint supportive supervision visits to trained RDVs to provide support on RMU with special emphasis on dispensing and counseling services, storage conditions, and segregation of expired drugs. Although it is early to see impact of the training, there are indications that RDVs are improving as the visiting teams saw that dispensing and counseling at the rural shops have become more patient-centered.

Considering the importance of these trainings to increasing access and quality of pharmaceutical services, SPS has plans to expand the training program and other support to RDVs located in the other regions of the country.

Promoting Rational Medicines Use

Irrational use of medicines leads to increased morbidity and mortality, increased direct and indirect costs and reduced availability of medicines, increased incidence and prevalence of adverse drug reactions and antimicrobials resistance, and could lead to mistrust between clients and health facilities. Irrational use of medicines in Ethiopia is a widespread problem at all levels of the health care system. Medicine use can be improved and wastage reduced if principles of good medicine management and use are followed. This was evident from the baseline survey on medicines use that was carried out by SPS that showed inadequacies on medicines dispensing, labeling, and counseling practices of service providers.

As an intervention for this, SPS developed a medicines dispensing and counseling job aid, accompanied by a checklist for service providers. The job aid and checklists

assist, monitor, and remind health care providers about good dispensing practices and help improve clients' knowledge about their medicines.



Also as part of the intervention, 200 model health facilities were to receive support to use standard prescription paper. An electronic copy of the standard prescription form was sent to PFSA hubs which distributed them to the 200 model health facilities which are now using them. In the reporting period, 185 facilities received standard treatment guideline (STGs) along with the electronic copy of prescription forms, (93 percent of the

plan's target). Medicines dispensing and counseling job aids that were distributed to the health facilities helped the health facilities to improve dispensing counseling. Reports from 105 facilities note that labeling and dispensing counseling practices have improved in the health facilities thanks to this intervention. The purpose of this intervention is to improve the safe use of medicines by empowering clients with knowledge about their medication.

Medicine use assessments at health facilities investigate medicine use patterns, prescribing behavior, dispensing practices, and availability of key medicines to treat basic health problems. In addition to identifying problems and guiding the development of related interventions, the assessment results allow health facility leaders, such as the executive officer, medical director, and the DTC, to evaluate the health facility's performance compared to World Health Organization (WHO) or national standards. Indicators identify performance problems and guide subsequent interventions and can serve as supervisory tools to follow performance improvements. In the reporting period, SPS supported 17 DTCs to conduct prescription audits. The audit results indicated areas that needed targeted interventions.

In the reporting period, a consultative workshop was organized by SPS in collaboration with FMHACA to review the draft manuals on good prescribing and dispensing practices. The workshop brought together a mix of professionals including physicians, pharmacists, druggists, and nurses. The manuals are relevant tools to help prescribers look critically at their current prescribing behavior and to lay down guidelines for good prescribing and dispensing practices in Ethiopia.

With the objective of educating the general public on the rational use of medicines, SPS collaborated with FMHACA and the Ethiopian Television and Radio Agency to present a one-hour talk on RMU, which allowed SPS and FMHACA experts to respond to questions raised from the program facilitator and from the general public. The audience feedback was encouraging and indicated that it was a very successful intervention in promoting RMU. There had been a series of interventions using electronic and print media on different aspects of RMU, self-medication, adherence to treatment, and AMR.

During the plan period, SPS regional pharmaceutical associates visited and supported 167 health facilities (83.5 percent of the target set for the plan year) to

help implement rational dispensing practices and patient counseling as well as strengthening DTCs. ARV dispensing units of health facilities were supported in updating patient information sheets and uploading patient data to the computerized antiretroviral dispensing tool (ADT). Moreover, data have been collected from health facilities to assess prescribing pattern using prescribing indicators. Pharmacy professionals at the targeted facilities have been mentored to improve their dispensing and counseling skills.

Information, education, and communications materials containing basic facts on AMR for health care providers were distributed to 48 health facilities to help improve the rational use of antibiotics. Similarly, national and essential medicine lists, AMR brochure, an ADR reporting form, and information, education, and communication materials on ARVs were supplied to the health facilities (health centers and primary hospitals). After receiving the materials, 29 health facilities reported initiated patient education sessions by with the aim of promoting RMU.

A high-level AMR advocacy and intervention seminar on AMR and its link to being found in livestock and animal products that focused on the consequences to public health in Ethiopia was conducted in collaboration with the School of Pharmacy and School of Veterinary Medicines, Addis Ababa University, in collaboration with SPS. The seminar's objectives were to disseminate information on the magnitude and causes of AMR to raise awareness and initiate advocacy on AMR.

SPS closely collaborated with the FMOH to celebrate World Health Day using the theme: "Antimicrobial resistance: No action today, no cure tomorrow." The celebration was accompanied with presentations and was attended by about 100 invited guests drawn from the FMOH, hospitals, health centers, and the pharmaceutical industry, academia, research institutions, regulatory agency, professional associations, NGOs, UN organizations, traditional medical practitioners, and the media.

Strengthen Pharmaceutical Manpower

Since the start of its operation in Ethiopia, SPS has been providing both pre-service and in-service training for health workers, mainly pharmacy professionals, as part of its institutional capacity building efforts. Pre-service ART training for graduating pharmacy students has been carried out by SPS in collaboration with the schools of pharmacy of public universities. Likewise, the in-service training program of SPS that was started a few years back has helped pharmacy personnel from public and private health institutions to develop their skills.

In COP10, a training of trainers' course on antiretroviral therapy (ART) for pharmacists was organized by SPS for the country's regional pharmaceutical associates with the objective of building their capacity on ART



SPS Regional Pharmaceutical Associates attending TOT

training. The training also provided an opportunity to train university staff who will constitute the trainers' pool for future ART trainings. In particular, the training addressed capacity-building challenges in the national strategy for scaling up comprehensive HIV/AIDS services. Building the capacity of health care providers is the basic part of the strategy to scaling up services and needs due attention from all stakeholders. As a result of the training, the pharmaceutical associates facilitated training requests from SPS collaborators and partners in the regions on their own.

The newly developed national ART training material (Antiretroviral Therapy Training for Pharmacists), which was developed by SPS in collaboration with the FMoH and other partners, was used for the training. A total of 18 trainees successfully completed the course and were certified. Also, 10 trainers/facilitators helped with the training along with 13 expert patient trainers who worked during the latter part of the training.

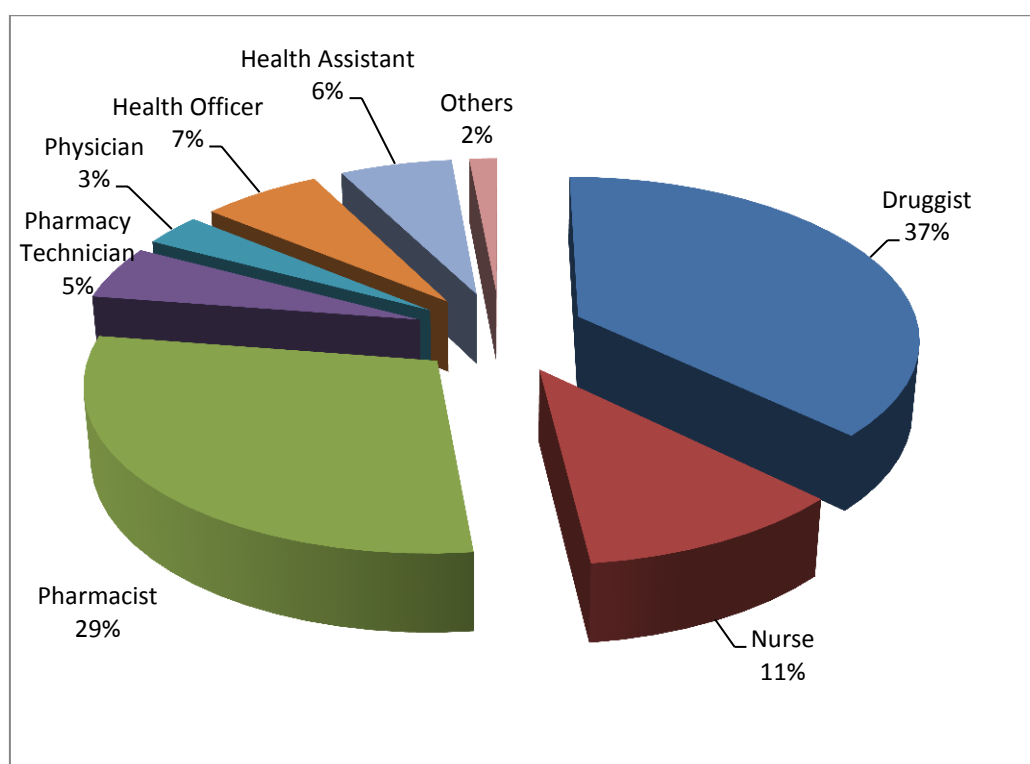


Figure 3. Distribution of in-service training participants by profession, October 2010-September 2011



Pre-service ART training participants

and Education Center for Health [I-TECH], Johns Hopkins University [JHU], and UCSD). In total, 1,540 professionals were trained. Nearly half (48 percent) of all trainees was from Oromia region; 40 percent of trainees were druggists and pharmacy technicians, while 31 percent were pharmacists. SPS receives frequent requests from USG implementing partners (ICAP, I-TECH, JHU, UCSD) to support trainings in their respective catchment areas for pharmacy and nursing personnel on drug supply management, ADT/electronic dispensing tool (EDT), RMU and dispensing counseling, ARVs and related commodities, etc. SPS willingly participates in these trainings and its achievements in this particular activity have reached 192.5%.

Similarly, a week-long pre-service ART training session was organized for Addis Ababa University graduating students in two parallel sessions. A total of 61 pharmacy graduates successfully completed the course and were duly certified. This program was organized in collaboration with John Hopkins University-TSEHAI.

PFSA, SPS, and WHO set up a collaborative agreement to conduct training on RMU/DTC for health care providers working in health centers was successfully carried out during the reporting period. The training was carried out in 7 rounds, and a total of 181 health professionals representing 91 public health centers, 4 hospitals, 6 RHBs, and 1 regional PFSA were trained. The objectives of the training was to promote the RMU at the prescribing, dispensing, and patient-use levels at health centers, and to enable health centers to establish and strengthen DTCs. Similarly, a memorandum of understanding was signed with JHU-TSEHAI to collaborate on providing training on adherence, DIS, and AMR in Benishangul, Addis Ababa, SNNP, and Gambella regions. This is an exemplary collaboration to create synergy between two USG PEPFAR implementing partners that are funded through CDC and USAID.

Mid-course competency tests have been recently introduced for pharmacy personnel during ART in-service trainings on ARV drugs interactions, major side effects, and their management. The purpose of this test was to help trainees assimilate practical pharmaceutical care aspects of the main course points and allow trainees to become versed in

As part of its capacity building efforts, SPS collaborated with partners and provided trainings on DTCs and standard operating procedures for health professionals drawn from public and private health facilities. In the reporting year, 55 training events were organized in collaboration with PFSA, WHO, RHBs, the Clinton Foundation HIV/AIDS Initiative (CHAI), the Ethiopian Catholic Church, HIV/AIDS Care and Support Program, and other US government (USG) partners (International Center for AIDS Care and Treatment Program [ICAP], International Training



managing drug interactions and side effects. Moreover, the tests helped the facilitators in identifying those students who needed closer follow up. These competency tests are provided in addition to the usual pre- and post-training tests.

SPS is currently working with PFSA to institutionalize DTCs in the health care system of the country. This effort included building the staff capacity of PFSA, RHBs and zonal health offices (ZHOs) to actively participate in DTC functions. so as to create a team with members from PFSA, RHBs or ZHOs, and SPS at each of the PFSA branches to organize training and provide the necessary technical support to DTCs at nearby health facilities. Accordingly, a training of trainers course on DTC was organized for eight days by PFSA and SPS for 29 health professionals drawn from PFSA, RHBs, and ZHOs.

SPS jointly with FMHACA organized three training events on proper medicine use for health care providers from private hospitals. The training's objective was to create awareness among physicians, pharmacy professionals, health officers and nurses working at private health facilities to enable them promote proper medicines use through rational prescribing and dispensing of medicines. A total of 89 health professionals participated.

Promote Recognition and Prevention of Adverse Drug Reaction and Pharmacovigilance

Reporting of adverse drug events (ADEs) is low in Ethiopia. To address the challenges of underreporting, SPS, in collaboration with the FMHACA and RHB, technically supported 27 health facilities to conduct face-to-face discussions with health professionals of the respective facilities on ADRs. Over 100 health professionals attended the sessions and discussed challenges and ways to enhance drug safety monitoring and reporting of ADEs. Besides discussions on issues related to ADR, the forums were used to create awareness among health providers on detection and analysis of ADR.



*National Pharmacovigilance framework
workshop participants*

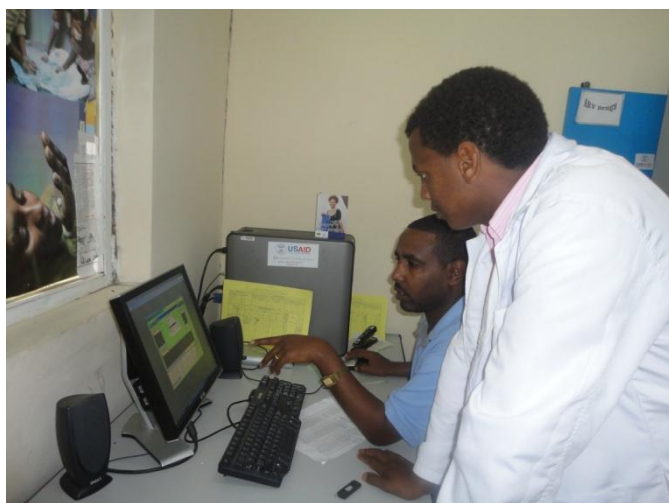
Technical assistance (TA) was provided to six major health facilities in ADR monitoring and reporting. Allergy cards were developed and distributed to 29 public and private facilities in Addis Ababa, together with a job-aid tfor health service providers for patient education on drug allergy to be used during the regular morning patient health education sessions and also to be posted in waiting rooms. The Ethiopian Drug List and the current edition of FMHACA's bulletin were also distributed together with the allergy cards. A pharmacovigilance newsletter has been finalized and sent for printing.

In the reporting period, a total of 21 facilities sent 70 ADR reports that were entered into the WHO Vigibase at *the* Uppsala Monitoring Centre and the second summary of adverse drug events using the 136 reports that were sent to the authority in 2010..

A consultative workshop on standardizing course content of teaching institutions on pharmacovigilance was organized by FMHACA in collaboration with SPS. It focused on having Ethiopian teaching institutions standardize the information they deliver on adverse event monitoring to the students during pre-service training. That would equip students with the knowledge necessary to participate in drug safety monitoring while they are in practice. The participants were instructors drawn from government and privately owned medical schools and pharmacy colleges as well as Regulatory Information Development and Dissemination team of FMHACA. Another consultative workshop on developing a national pharmacovigilance framework was also organized with the help of SPS.

Strengthen Patient-Focused Pharmaceutical Management Information System at Facility Level

SPS has been supporting the generation, collection, and management of patient medication records at pharmacy level since the start of ART program in Ethiopia. The patient medication record enabled recording of information related to patient demographic characteristics, medicines dispensed, and RMU. For the purpose of recording and reporting of pharmaceutical information originating from ART pharmacies, SPS has developed and implemented different management information system tools, including ADT and EDT.



RPMA providing TA on how to use EDT for ADR, adherence and other activities

During the plan period, SPS provided support to over 500 ART sites (400 sites using paper-based tools and 165 sites using electronic tools) with the help of its RPMAs and data managers stationed in the regions and in Addis Ababa. There are 5 data managers and 12 RPMAs that support the PMIS activities in the country. The support includes provision of different forms, computers, printers, backup drives, and RW-CDs. SPS also provided some sites that have a heavy patient load with both internet and telephone connections. The sites that have computers are provided with training

and software support to enable them to properly use ADT. The remaining sites are using paper a based system.

Manual PMIS tools were distributed to 565 health facilities to maintain record-keeping on patient information. Six private hospitals that started pediatric ART service were supported by providing the necessary manual form of ADT and giving training on the use of the tools to their pharmacy personnel.

In the reporting period, installation of the EDT continued and conversion from ADT to EDT was carried out at eight more facilities, bringing the total number of facilities



EDT installation at Debreberhan hospital

programs, maintaining computers; providing support on EDT, fixing database problems; and providing TA to improve data quality. The managers also gave an onsite demonstration of data recording, documentation, and reporting on PMIS

operating EDT to 38. Three facilities have started real-time dispensing, in which adherence data can easily be generated and clients who missed their appointments can easily be identified. EDT implementation support was also given to 10 health facilities by data managers. In addition, the data managers provided supportive supervision to 133 ART sites in their respective catchment areas. Their support focused on the following areas: updating antivirus formats for new data clerks; and collection of monthly pharmacy ART patient uptake reports.

Although not planned for COP10, orientation on the revised formats of PMIS was given to health professionals who are working for the Supply Chain Management System (SCMS) and support PFSA head office and hubs as well as the data clerks. The revised formats are a Monthly ARV Drugs Activity Report for Adults and Pediatrics, and ARV Drugs Dispensing Register for Adults and Pediatrics. The main purpose of these revised formats is to capture ART data on patient and regimen profiles.

During the ART basic training at Yirgalem Hospital, topics on pharmaceutical management information system (PMIS) were discussed with pharmacy personnel to create awareness on tracking medicine-related information so as to promote treatment adherence and avoid stock outs. A total of 34 participants attended the event.

Collection and compilation of national and regional ART patient uptake, including cumulative regimen reports continued during the reporting period. The information was collected from 565 ART sites, compiled and shared with SPS management, USAID, SCMS, Regional Logistic Associates, RHBs, HCSP, I-TECH Ethiopia, CHAI, regional HIV/AIDS Prevention and Control Offices (HAPCOs) and Johns Hopkins University-Ethiopia.

Support FMHACA to Strengthen Pharmaceutical Management Capacity and to Promote Pharmaceutical Good Governance

The senior SPS pharmacist seconded to FMHACA spearheaded the preparation of facility standards for health posts, health centers, primary hospitals, general hospitals, and comprehensive specialized hospitals. Likewise, a regulatory standard for specialty centers (new type of health facilities which are positioned between general hospital and ambulatory specialty clinics with inpatient and pharmacy services) has been developed. Six rounds of regional consultative workshops were conducted on specialty centers and ambulatory health care standards. These health

facilities have their own pharmacy section, though the scope of the pharmacy section varies. FMHACA has acknowledged SPS and USAID-Ethiopia for their continued technical support in the development of various regulatory standards. In total, 13 standards have been developed to date (five approved by FMoH executives and eight are scheduled for approval).

Many of the health care facilities in Ethiopia face severe shortage of storage facilities while pharmaceutical waste in the form of expired and damaged drugs and supplies occupies much valuable space. An absence of clear policy, regulations, and guidelines on pharmaceutical waste disposal has prompted health facilities to accumulate and hold to these unfit-for-use commodities for an extended period of time. To tackle this problem, SPS has supported FMHACA to draft a national framework and disposal directives on pharmaceutical waste management. The national framework is intended to promote safe and proper management of medicines waste in all health care settings of Ethiopia, while the directive provides direction on the implementation of safe disposal of unusable pharmaceuticals in Ethiopia.

In the reporting period, a document on Medicines Waste Management and Disposal Directive has been finalized, approved, and sent for printing after soliciting feedback from the concerned stakeholders through a national consultative workshop that was organized by SPS and FMHACA. The workshop's 36 participants were drawn from the Ministry of Health, the Environmental Protection Agency, Regional Health Bureaus, FMHACA Branches, both private and public health facilities, private importers/wholesalers, pharmaceutical manufacturers, retail medicine outlets, and SPS. Once endorsed by the concerned regulatory bodies, these documents are expected to serve as standard guides for management of pharmaceutical waste for the country.

SPS Office Management and Program Support Operations

In the reporting period, the SPS statistical bulletin was printed and distributed to stakeholders, partners, and USAID-Ethiopia. Second in a series, the bulletin presents summarized statistical data on RPM Plus and SPS support in Ethiopia since 2005. The bulletin is expected to serve as a reference material and provide users with insight into the results of interventions by SPS–Ethiopia with funding from PEPFAR/USAID–Ethiopia.

Three joint mentoring and supportive supervision visits to seven health facilities were carried out with PFSA, RHBs, ZHOs, and USAID | DELIVER to provide technical support on DTC and IPLS. This joint venture helped SPS to ensure intra-organizational collaboration and coordination among PFSA, RHB/ZHO, and partners in its support to health facilities.

The RPMAs of SPS participated in catchment area meetings of their respective RHBs' annual review meetings that were conducted to review the Health Sector Development Program (HSDP) III performance report, the Growth and Transformation plan for next five years, HSDP IV, 2010 annual plan, and status of ongoing projects. The Amhara RHB awarded SPS a certificate of appreciation for the



support it provided to the regional government in implementing HSDP III. It has also received certificates of recognition from two hospitals

(Debretabor and Bule Hora) for the technical and material support it rendered in developing facility-specific drug list and establishment of DIS.

In the reporting period, SPS management produced and submitted COP09

National consultative workshop participants

performance report to USAID-Ethiopia. The report

summarized the major activities and results accomplished by SPS–Ethiopia in collaboration with Ethiopian Government stakeholders and other partners for the period October 2009 to September 2010. Similarly, the SPS COP10 plan was prepared in close consultation with its Chief Technical Officer at USAID-Ethiopia; this was followed by preparation of joint plans with its major government stakeholders (PFSA and FMHACA). SPS conducted its COP10 planning meeting to introduce the plan to its staff and develop detailed implementation work plan with the help and full participation of its staff. Each SPS staff member has prepared his/her own individual work plan as a means of implementing the COP10 SPS–Ethiopia plan.

SPS was represented by its regional pharmaceutical associates to attend regional meetings organized by government partners. For instance, RPMA in the northwestern Ethiopia participated in the regional HAPCO 2004 EFY annual planning meeting to introduce thematic areas of Strategic Performance Monitoring (SPM) II, 2012 annual plan and collect plans of partners working in the area of HIV/AIDs to incorporate with their plan. At the meeting, SPS major program and activity areas were presented and discussed.

During COP10, SPS produced a variety of pharmaceutical related publications and reports.

Table 1. List of Publications Produced in COP10

Title	Author	Date
Strengthening Pharmaceutical Systems – Ethiopia Annual Report	SPS–Ethiopia	November 2010
Statistical Bulletin of SPS program	SPS–Ethiopia	January 2011
Rural Drug Vendors Training Curriculum	SPS-Ethiopia and FMHACA	March 2011
Drug Formulary for Rural Drug Vendors (RDV)	SPS-Ethiopia and FMHACA	March 2011
Facility specific drug lists (six facilities)	Facility DTCs	Various
Abstract on Outcome of the Live ETV Education on Rational Use of Medicines	Tenaw Andualem; Wolde Aregay, Mengistab; Birhanu, Habtamu	April 2011
Trends in Antiretroviral Drugs Prescribing at Public Health Facilities in Ethiopia: Compliance to Treatment Guidelines	Hailu Tadege and Negussu Mekonnen	April 2011
Article on “ <i>The Ethiopian Hospitals Reform: a tool for improving the Pharmacy services</i> ”	Ayalew Adinew	May 2011
Terms of reference and action plan for APTS implementation guide line development	Amhara RHB	May 2011
Report on Magnitude of and Contributing Factors to Antibacterial Resistance in Ethiopia	Tenaw Andualem , Negussu Mekonnen, Daniel Gabriel, Mohan Joshi, Douglas Keen, David Lee	June 2011
Capacity-building for Country and Regional Level Advocacy and Interventions to Contain Antimicrobial Resistance in Africa	Mohan P. Joshi, Terry Green, Oliver Hazemba, Rosalind Kirika, Tenaw Andualem, Wonder Goredema, Gabriel Daniel, Negussu Mekonnen	June 2011
The level of ART adherence and associated factors among ART Clients at health centers of Bahir Dar city, North West Ethiopia	G. Sisay, Y. Berhane, S. Lema, T. Andualem, S. Kellerman	June 2011
<i>Workshop Proceedings: Development of Draft Proclamation for Institutionalization of Auditable Pharmacy Services and Transaction Systems (APTS).</i> Submitted to the U. Agency for International Development by the Strengthening Pharmaceutical Systems Program. Arlington, VA: Management Sciences for Health	Hailu, Tadege, Ayalew Adnew, Getahun Sisay, Solomon Nigussie, and Bizualem Adam	2011
Training Report: Rural Drug Vendors, Oromia Regional States	Getachew Ayalew	August 2011
Instructional Design and Assessment: Strengthening Pharmaceutical Care Education in Ethiopia through Instructional Design	Peggy Soule Odegard, Hailu Tadege, Don Downing, Hailemeskel Mekonnen, Negussu Mekonnen, Rebecca Bartlein, Andy Strergachis	2011

Support to Pharmaceutical Fund and Supply Agency

SPS provided financial and technical support to the national consultative workshop on the EHRIG that was organized by PFSA and FMoH. A total of 70 participants drawn from FMoH, PFSA, Regional Health Bureaus and selected health facilities attended the workshop. The support of SPS towards implementing the EHRIG was a logical continuation of SPS efforts to put the EHRIG pharmacy information into practice.

In the reporting period, joint PFSA–SPS meetings were organized to assess the progress of plans between PFSA and SPS at regional level in the presence of the PFSA branch managers, forecasting and capacity building officers, assistant hub managers seconded by SCMS, and SPS Regional Pharmaceutical Associates. Each planned activity and obstacles for its accomplishment were discussed by the team and solutions to problems indicated.

Support to the Ethiopian Pharmaceutical Association



SPS supported the EPA to conduct two continuing pharmacy education sessions on “communication skills to enhance pharmaceutical care” and “professionalism and regulation in pharmacy practices: international perspective.” The sessions were attended by 108 professionals (60 practitioners working in retail drug outlets

attended the first session and 48 pharmacists working in different sectors attended the second one). The session helped the participants to recognize pharmaceutical care as an evolving model of pharmacy practice in which pharmacists are expected to establish clinical relationships with patients as well as to recognize the inseparable nature of professionalism and regulation, including self-regulation.

The EPA held its 37th annual conference with the theme: Pharmaceutical Sector Governance for Health and Economic Development of Ethiopia. . A key topic raised at the annual conference was pharmaceutical governance in Ethiopia as compared to pharmaceutical governance and service delivery elsewhere. Different continuing education sessions were also facilitated by experts.

CHALLENGES AND CONSTRAINTS

SPS-Ethiopia has encountered the following challenges and constraints while implementing its COP 2010 plan—

- Delay in implementing the joint work plan that SPS developed with partners, mainly with PFSA and FMHACA,
- Delay in the approval of COP10 work plan due to the need to revise the plan so that it better addressed Mission expectations and requirements.
- High pharmacy staff turnover in health facilities and a lack of commitment to implement planned activities as per the scheduled time frame, especially those activities that need practical involvement of pharmacy professionals, such as dispensing and counseling.
- Resignation and reassignment of DTC trained staff at health facilities led to delays in DTC-related activities; inability to sustain functionality of DTCs and continuity of their activities due to weak follow-up at some hospitals.

MAJOR ACTIVITIES PLANNED FOR COP11

Based on the lessons learned from past performances and considering fund availability, SPS will strive to perform the following activities between October 2010 and September 2011. Following is a synthesis of major planned activities—

- Provide training on leadership, management, supervision, and team building to managers drawn from major stakeholders
- Support consultative meetings on medicines regulatory issues between FMHACA and private pharmacies, medicines manufacturers, importers, distributors, and retailers
- Support policy/legal documents dissemination workshops pertinent to pharmacy service standards and regulations
- Update the STGs and national drug list
- Facilitate drug list development workshops
- Provide TA to facilities in the preparation of health facility specific drug lists and support printing of drug lists
- Work with governmental and nongovernmental organizations to explore the possibility of implementing pharmacy service accreditation
- Provide pharmaceutical ethics training to Ethiopian Druggists Association (EDA) and EPA members
- In collaboration with PFSA and RHBs, conduct supportive supervision to selected sites to strengthen DTCs
- In collaboration with PFSA and RHBs, organize regional meetings for the exchange of best practices among DTCs; provide incentives (computers/LCD projectors) to best performing DTCs
- Scale up establishment and operation of additional DTCs
- Provide new and refresher/replacement trainings
- Support ABC /VEN analysis and prescription review by DTCs
- Support health facilities to start using APTS
- Train service providers from DTC sites on EHRIG pharmacy material and APTS
- Support RHB to institutionalize APTS
- Develop SOPs for implementation of EHRIG pharmacy material
 - Support regional for experience sharing and exchange of best practices
 - Strengthen existing EHRIG intervention sites through mentoring and supportive supervision
 - Document and share success stories

- Provide dispensing shelves, filing cabinets, basic dispensing furniture, computers with printers
- Training of graduating pharmacy students in ARVs, malaria, tuberculosis, opportunistic infections, and rational medicine use; containment of antimicrobial resistance, adherence, and pharmaceutical good governance
- Conduct in-service training on clinical pharmacy/pharmaceutical care to EHRIG-implementing sites in collaboration with schools of pharmacy.
- Train pharmacy professionals from public and private health facilities and RHBs on RMU and ART
- Provide trainings to mid-level pharmacy personnel to improve quality of service (fill knowledge gaps)
 - Conduct operations research on pharmacy personnel task shifting
 - Organize continuing education sessions to pharmacy practitioners in collaboration with EPA
- Support EPA to conduct activities related to RMU during its annual scientific conference
- Development of the competence of personnel working in pharmaceutical supply chain in the private sector (“non-traditional health cadres to support pharmaceutical management functions”)
- Roll out of EDT to all sites with computerized system (ADT)
 - Provide on-the-job and off-the-job training and mentoring to sites with EDT
 - Collaborate with a local IT firm and partners to customize ADT/EDT to support dispensing of all essential medicines at outpatient department (OPD) pharmacies as part of implementing EHRIG pharmacy material
 - Print and distribute different data capturing and reporting forms to all ART sites
- Actively disseminate reports generated to relevant users (USAID, FHAPCO, RHBs, PFSA, HFs, and USG partners) and also ensure that the reports are made available to decision makers
- Provide TA to implement real-time dispensing using electronic tool and maintain patient-medication records for chronic diseases in addition to HIV/AIDS
- Train doctors, health officers, and nurses to rationalize their prescribing behavior
- Conduct rapid assessment to determine current prescribing trends
- Standard treatment guidelines STGs/protocols, prescribing manual
- Provide ARV drugs prescription forms to ART sites
- Electronic prescription forms to all facilities
 - Provide TA in the implementation of good dispensing practices
- Support the printing and distribution of dispensing aids (formularies)

- Produce and disseminate electronic and printed IEC materials on ethical (prescription) and over-the-counter (OTC) drugs for patient education in collaboration with FMHACA
- Strengthen the National Advisory Committee on AMR to carry out its mandate effectively (study tour, incentives)
- Support regular meetings of the National Advisory Committee
- Conduct the two rounds of trainings on AMR for journalists per year
- Pilot regional AMR containment interventions with ORHB, Jimma University, and FMHACA
- Support printing and distribution of ADR reporting forms (yellow form) to health facilities
- Provide trainings on medicines safety (recognition, prevention, and documentation, and monitoring and reporting of ADR) to health professionals from public and private hospitals
- Provide support to develop pharmacovigilance (PhV) database
- Provide TA in use of information generated from PhV database to solve drug related problems (medication errors, product quality, lack of efficacy and ADR) in collaboration with PQM.
- Popularize PhV framework through workshops and trainings
- Provision of TA to FMHACA to initiate/establish active surveillance system
- Scale up establishment and operation of Drug Information Services in selected hospitals throughout the regions
- Conduct operations research on drug utilization to optimize use of medicines and treatment outcomes
- Popularize the waste disposal framework and directives prepared with TA from SPS using workshops and provide trainings to health care providers and other relevant stakeholders
- Develop a national framework for clinical waste management
- Provide training to RDVs in Oromia and other regions
 - Revise/update RDV training materials
 - Follow-up and support to trained RDVs
 - Conduct assessment to examine RDVs training outcome
 - Print and distribute RDV formularies
- Make an assessment and produce a proposal how to institutionalize the trainings and make them part of the requirement for re-registration